

Remarks

This Supplemental Amendment is submitted in view of the interview conducted with the Examiner in the case on August 26, 2008. That interview is also summarized herein.

Status of All of the Claims

Below is the status of the claims in this application.

1. Claim(s) pending: 68-104.
2. Claim(s) cancelled: 1-67.
3. Claim(s) added: None.
4. Claims withdrawn from consideration but not cancelled: None.

Examiner Interview

Applicant acknowledges and thanks the Examiner for the interview conducted on August 26, 2008. During that interview, the cited prior art was generally discussed, and applicant pointed out that the cited art did not disclose the use of a solid, transparent or translucent material to allow the user to view the movement of a blood sample from an edge, sample application port through the capillary channel to a fill line. It was noted that the solid viewing material was not expressly included in claim 82, and that is the subject of the amendment made herein.

Claim Amendments

The claims previously presented have been amended in one respect, namely, the fifth paragraph of claim 82 has been amended as follows:

a solid, transparent or translucent viewing material extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel, said strip body defining a viewing area comprising a portion of the viewing material allowing continuous visualization of the capillary channel from a portion thereof at or generally adjacent the sample

application port, up to and including said working electrode and at least a portion of said counter electrode,

Patentability Over the Art

The present invention comprises a capillary-fill, electrochemical test strip in which the movement of a blood sample to a fill line can be visualized to provide confirmation to the user that sufficient blood has been dosed to the strip, and has reached the required test area. The claims require a solid, transparent or translucent portion which overlies the internal capillary chamber.

All of the cited references have a common failing with respect to anticipation of the present claims - a blood sample can not be viewed through a solid, transparent or translucent material as the sample fills a capillary channel inwardly from the edge of a test strip to a fill line:

- Diebold '999 includes a capillary channel defined by a cutout 49 sandwiched between top and bottom layers; there is no indication that either of the outer layers is transparent or translucent, or that there is any kind of fill line, and indeed the capillary channel is shown as being hidden (see dashed lines in Fig. 6) by the outer layers.
- Hodges '102 and '420 show sandwich-type test strips in which the interior, circular chamber is hidden by the outer layers and consequently there is no fill line.
- Charlton '031 shows a test strip having a base 36 and a lid 46, with the lid embossed to form a concave space 48 constituting the capillary channel. Charlton does not identify any solid portion(s) of the base or lid as being transparent or translucent, and does not identify a fill line.

- Ikeda '895 discloses a sandwich-type test strip with top and bottom layers 6 and 9 and an interior chamber 11-11b. There is no indication that any portion of the layers 6 or 9 are transparent or translucent, and there is no fill line.
- Yoshioka '103 has a similar sandwich-type design, and fails to show that any portion of the outer layers 1 or 4 are transparent or translucent or that there is a fill line.
- Seshimoto '445 discloses a device including a bottom plate 21 and a top plate 18, with testing electrodes 11a-11c received in an interior passage 14. Sample is received at top opening 12 and then directed down through passage 13 to the interior 14. There is nothing in Seshimoto '445 to suggest that any part of plate 21 or plate 18 is transparent or translucent to allow viewing of the sample as it moves along interior passage 14, or that there is a fill line.
- Columbus '457 provides a device in which sample is received through a top opening 42 or 42' and conveyed through a capillary channel defined by surfaces 34 and 36. There is no indication that the top 30 (including surface 34) or the bottom 32 (including surface 36) is transparent or translucent, or that there is a fill line.
- Galen et al. '949, and '692 disclose top-dosing strips with openings 6, 7 and 11 extending from a top substrate through to a bottom substrate. There is no solid, transparent or translucent portion to allow blood to be visualized as it fills a capillary channel, and no fill line to indicate when sufficient filling has occurred.

In comparison, the present invention provides a uniquely advantageous design for a capillary fill test strip in which the filling of the strip is viewable to show if adequate filling has occurred to conduct a test. Test strips which do not adequately fill can produce inaccurate results. The present invention provides an elegant solution to this problem by allowing the

users to visually watch the blood fill the test strip, and to readily determine whether the blood makes it to the fill line – the indicator when enough blood has been added.

Further consideration of the application and allowance of claims 68-104 is respectfully requested. The examiner is requested to contact the undersigned by telephone if it appears that issues may thereby be more readily resolved leading to allowance of this application.

Respectfully submitted,

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